

Pantoloc control[®]

20 mg gastro-resistant tablets

Pantoprazole

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to use PANTOLOC Control carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 2 weeks.
- You should not take PANTOLOC Control tablets for more than 4 weeks without consulting a doctor.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What PANTOLOC Control is and what it is used for
2. Before you take PANTOLOC Control
3. How to take PANTOLOC Control
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symptoms after just one day of treatment with PANTOLOC Control, but this medicine is not meant to bring immediate relief.

You should not take it as a preventive measure.

If you have been suffering from repetitive heartburn or indigestion symptoms for some time, remember to see your doctor regularly.

Using other medicines

PANTOLOC Control may stop certain other medicines from working properly. Tell your doctor or pharmacist if you are using any medicines containing one of the following active substances:

- ketoconazole (used for fungal infections).
- warfarin and phenprocoumon (used to thin blood and prevent clots). You may need further blood tests.
- atazanavir (used to treat HIV-infection). You must not use PANTOLOC Control if you are taking atazanavir.

Do not take PANTOLOC Control with other medicines which limit the amount of acid produced in your stomach, such as another proton pump inhibitor (omeprazole, lansoprazole or rabeprazole) or an H2 antagonist (e.g. ranitidine, famotidine).

However, you may take PANTOLOC Control with antacids (e.g. magaldrate, alginic acid, sodium bicarbonate, aluminium hydroxide, magnesium carbonate, or combinations thereof), if needed.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This also includes herbal or homeopathic remedies.

1. WHAT PANTOLOC CONTROL IS AND WHAT IT IS USED FOR

PANTOLOC Control contains the active substance pantoprazole, which blocks the 'pump' that produces stomach acid. Hence it reduces the amount of acid in your stomach.

PANTOLOC Control is used for the short-term treatment of reflux symptoms (for example heartburn, acid regurgitation) in adults.

Reflux is the backflow of acid from the stomach into the gullet ("foodpipe"), which may become inflamed and painful. This may cause you symptoms such as a painful burning sensation in the chest rising up to the throat (heartburn) and a sour taste in the mouth (acid regurgitation).

You may experience relief from your acid reflux and heartburn symptoms after just one day of treatment with PANTOLOC Control, but this medicine is not meant to bring immediate relief. It may be necessary to take the tablets for 2-3 consecutive days to relieve the symptoms.

2. BEFORE YOU TAKE PANTOLOC CONTROL

Do not take PANTOLOC Control:

- if you are allergic (hypersensitive) to pantoprazole, to soya or to any of the other ingredients of PANTOLOC Control (listed in section 6 'What PANTOLOC Control contains').
- if you are taking a medicine containing atazanavir (for the treatment of HIV-infection).
- if you are under 18 years of age.
- if you are pregnant or breast-feeding.

Take special care with PANTOLOC Control

Talk to your doctor first if:

- you have been treated for heartburn or indigestion continuously for 4 or more weeks
- you are over 55 years old and taking non-prescription indigestion treatment on a daily basis
- you are over 55 years old with new or recently changed symptoms
- you have previously had a gastric ulcer or stomach surgery
- you have liver problems or jaundice (yellowing of skin or eyes)
- you regularly see your doctor for serious complaints or conditions
- you are due to have an endoscopy or a breath test called a C-urea test.

Tell your doctor immediately, before or after taking this medicine, if you notice any of the following symptoms, which could be a sign of another, more serious, disease:

- an unintentional loss of weight (not related to diet or an exercise programme)
- vomiting, particularly if repeated
- vomiting blood; this may appear as dark coffee grounds in your vomit
- you notice blood in your stools; which may be black or tarry in appearance
- difficulty in swallowing or pain when swallowing
- you look pale and feel weak (anaemia)
- chest pain
- stomach pain
- severe and/or persistent diarrhoea, because PANTOLOC Control has been associated with a small increase in infectious diarrhoea.

Your doctor may decide that you need some tests.

If you are due to have a blood test, tell your doctor that you are taking this medicine. You may experience relief from your acid reflux and heartburn

Using PANTOLOC Control with food and drink

The tablets should be swallowed whole with liquid before a meal.

Pregnancy and breast-feeding

Do not take PANTOLOC Control if you are pregnant, think you may be pregnant, or are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

If you experience side effects like dizziness or disturbed vision, you should not drive or operate machines.

Important information about some of the ingredients of PANTOLOC Control

PANTOLOC Control contains soya lecithin. If you are allergic to peanut or soya, do not use this medicine.

3. HOW TO TAKE PANTOLOC CONTROL

Always take PANTOLOC Control exactly as described in this leaflet. You should check with your doctor or pharmacist if you are not sure.

Take one tablet a day. Do not exceed this recommended dose of 20 mg pantoprazole daily.

You should take this medicine for at least 2-3 consecutive days. Stop taking PANTOLOC Control when you are completely symptom-free.

You may experience relief from your acid reflux and heartburn symptoms after just one day of treatment with PANTOLOC Control, but this medicine is not meant to bring immediate relief.

If you have no symptom-relief after taking this medicine for 2 weeks continuously, consult your doctor.

Do not take PANTOLOC Control tablets for more than 4 weeks without consulting your doctor.

Take the tablet before a meal, at the same time every day. You should swallow the tablet whole with some water. Do not chew or break the tablet.

Children and adolescents

PANTOLOC Control should not be used by children and young people under 18 years of age.

If you take more PANTOLOC Control than you should

Tell your doctor or pharmacist straight away. If possible take your medicine and this leaflet with you. There are no known symptoms of overdose.

If you forget to take PANTOLOC Control

Do not take a double dose to make up for the forgotten dose. Take your next, normal dose, the next day, at your usual time.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, PANTOLOC Control can cause side effects, although not everybody gets them.

Tell your doctor immediately or contact the casualty department at your nearest hospital, if you get any of the following **serious side effects**. Stop taking this medicine straight away, but take this leaflet and/or the tablets with you.

- **Serious allergic reactions (rare):** Hypersensitivity reactions, so-called anaphylactic reactions, anaphylactic shock and angioedema. Typical symptoms are: swelling of the face, lips, mouth, tongue and/or throat, which may cause difficulty

in swallowing or breathing, hives (nettle rash), severe dizziness with very fast heartbeat and heavy sweating.

- **Serious skin reactions (frequency not known):** rash with swelling, blistering or peeling of the skin, losing skin and bleeding around eyes, nose, mouth or genitals and rapid deterioration of your general health, or rash when exposed to the sun.
- **Other serious reactions (frequency not known):** yellowing of the skin and eyes (due to severe liver damage), or kidney problems such as painful urination and lower back pain with fever.

Side effects may occur with certain frequencies, which are defined as follows:

- very common: affects more than 1 user in 10
 - common: affects 1 to 10 users in 100
 - uncommon: affects 1 to 10 users in 1,000
 - rare: affects 1 to 10 users in 10,000
 - very rare: affects less than 1 user in 10,000
 - not known: frequency cannot be estimated from the available data.
- **Uncommon side effects:** headache; dizziness; diarrhoea; feeling sick; vomiting; bloating and flatulence (wind); constipation; dry mouth; bellyache and discomfort; skin rash or hives; itching; feeling weak, exhausted or generally unwell; sleep disorders; increase in liver enzymes in a blood test.

5. HOW TO STORE PANTOLOC CONTROL

Keep out of the reach and sight of children.

Do not use PANTOLOC Control after the expiry date, which is stated on the carton and the blister.

The expiry date refers to the last day of that month. Store in the original package in order to protect from moisture.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What PANTOLOC Control contains

- The active substance is pantoprazole. Each tablet contains 20 mg pantoprazole (as sodium sesquihydrate).
- The other ingredients are:
- Core: sodium carbonate (anhydrous), mannitol, crospovidone, povidone K90, calcium stearate.
- Coating: hypromellose, povidone, titanium dioxide (E 171), yellow iron oxide (E 172), propylene glycol, methacrylic acid-ethyl acrylate copolymer, sodium lauryl sulfate, polysorbate 80, triethyl citrate.
- Printing ink: shellac, red, black and yellow iron oxide (E 172), soya lecithin, titanium dioxide (E 171) and antifoam DC 1510.

– **Rare side effects:**
disturbances in vision such as blurred vision;
pain in the joints; muscle pains; weight
changes; raised body temperature; swelling of
the extremities; allergic reactions; depression;
increased bilirubin and fat levels in blood (seen in
blood tests).

– **Very rare side effects:**
disorientation; reduction in the number of blood
platelets, which may cause you to bleed or bruise
more than normal; reduction in the number of
white blood cells, which may lead to more fre-
quent infections.

– **Frequency not known:**
hallucination; confusion (especially in patients
with a history of these symptoms); decreased
level of sodium in blood.

If any of the side effects gets serious, or if you
notice any side effects not listed in this leaflet,
please tell your doctor or pharmacist.

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What PANTOLOC Control looks like and contents of the pack

The gastro-resistant tablets are yellow, oval, bicon-
vex film-coated tablets imprinted with "P20" on one
side. PANTOLOC Control is available in Alu/Alu blis-
ters with or without cardboard reinforcement.
Packs containing 7 or 14 gastro-resistant tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Detailed information on this medicine is available on the European Medicines Agency (EMA) web site:
<http://www.ema.europa.eu/>

The following recommendations for lifestyle and dietary changes may also help to relieve heartburn
or acid related symptoms.

- Avoid large meals
- Eat slowly
- Stop smoking
- Reduce alcohol and caffeine consumption
- Reduce weight (if overweight)
- Avoid tight-fitting clothing or belts
- Avoid eating less than three hours before bedtime
- Elevate bedhead (if you suffer from nocturnal symptoms)
- Reduce intake of food that can cause heartburn.
These might include: Chocolate, peppermint,
spearmint, fatty and fried food, acidic food, spicy
food, citrus fruits and fruit juices, tomatoes.